

**K201183 Vortex Radial Spray Catheter**Dec 7, 2020  
220 days to decisionK201183 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201183/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 1, 2020
Decision date	Dec 7, 2020
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>CSA Medical, Inc.</b>
Location	Baltimore, MD, US
Contact	Heather V Nigro
510(k) history	14 submissions · 14 cleared · 2007-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201183/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 15, 2026